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P&G Case 8141

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of	:	
Matthew Joseph Doyle et al.	:	Confirmation No. 8543
Serial No. 09/607,602	:	Group Art Unit 1644
Filed June 30, 2000	:	Examiner Patrick J. Noland

For Promoting Whole Body Health

REPLY BRIEF TRANSMITTAL

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed, pursuant to 37 CFR 1.193(b)(1), is the Reply Brief for the above application.

We do not believe a fee is due. If, however, a fee is due, the Director is authorized to charge any fee which may be required to Deposit Account No. 16-2480. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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Customer No. 27752

(ReplybriefTransmittal.doc)
(Last Revised 10/10/2003)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	09/607,602
Applicant(s)	Matthew Joseph Doyle et al.
Filed	June 30, 2000
Title	Promoting Whole Body Health
TC/A.U.	1644
Examiner	Patrick J. Nolan
Conf. No.	8543
Docket No.	8141
Customer No.	27752

REPLY BRIEF UNDER 37 CFR §1.193

THE COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INTRODUCTORY REMARKS

Submitted herewith is a reply brief in response to the Examiner's answer to the Appeal Brief filed in support of the Notice of Appeal filed February 13, 2003 for the above referenced application.

This reply brief is being filed within the two-month period from the mailing date of April 7, 2004 of the Examiner's answer and no fees are believed to be due. In the event that a fee is required, please charge Procter & Gamble Deposit Account No. 16-2480.

The reply brief begins on Page 3 of this paper.

REPLY BRIEF

The Examiner has maintained the rejection under 35 U.S.C. §102(b) of Claims 2-4 and 7 as being anticipated by Pan et al. (WO 97/16159) and by Singer et al. (US 5,364,616) and of Claim 2 as being anticipated by Tsujita et al, (JP 04089428A). It is contended that the presently claimed whole body health benefits are inherent in the referenced methods. It is further contended that the preamble of the present claims which recite the new use of promoting whole body health is not considered limiting. However, even if the preamble were considered limiting, it is the Examiner's position that although Appellants are claiming a new benefit of an old process, the method of promoting whole body health is not patentably distinct from the cited references, that is, inherent in the disclosed methods.

Firstly, Appellants respectfully request entry of an amendment to Claim 2 under 37 CFR §1.116 submitted concurrently in a separate paper. This amendment is believed to present the rejected claims in better form for consideration on appeal.

Claim 2 is amended to recite that the method of promoting whole body health is directed to subjects in need thereof and the topically applied composition comprises an amount of a host-response modulating agent effective to promote whole body health in said subjects. As clearly established in the record, the patients intended for the presently claimed method are subjects who are at risk for the development of one or more of systemic conditions selected from heart disease, stroke, diabetes, severe respiratory infections, delivery of premature or low birth weight infants heart disease, and post-partum dysfunction in neurologic and developmental functions. In contrast, the subjects intended in the referenced methods are those in need of treatment or prevention of non-systemic or localized conditions in the mouth such as plaque, gingivitis and periodontal disease. The amendment to Claim 2 also places the requirement for promotion of whole body health in the body of the claim and addresses the Examiner's concern regarding the preamble as a limiting element.

The present claims are directed to a new use, specifically a second medicinal use of a process namely topical administration to the oral cavity of a composition comprising a host response modulating agent such as a H-2 antagonist in an amount effective to promote systemic or whole body health in subjects in need thereof.

There is express authority under 35 U.S.C. § 100(b) for patentability of a **new use of a known process, machine, manufacture, composition or matter or material**. (emphasis added), as acknowledged for example by the Court in *Bristol-Myers Squibb v. Ben Venue Laboratories*. See also *Howes v. Great Lakes Press Corp.*, 679 F.2d 1023, 1029 (2d Cir.), which found that Howes' claim to a method which makes possible the faithful transfer of color art work to fabric by means of treated heat transfer paper was patentable because Howes created a **new use of a known process**. As stated therein:

> *Patents are not granted for the natural properties inherent in things existing in nature, although they may be granted for things an inventor does with those properties. An old material cannot be patented even though someone has discovered a hitherto unknown use for it, because the material was known. A new use for old material does not make the material patentable. But the new use or application of an old material may be patentable. Similarly, a process or method which involves only a new use of an old material is patentable. Federico, Commentary on the New Patent Act, 35 U.S.C.A. 1, 16-17 (1954). In our view appellant's process patent falls within this last description.*
>
> *The statutory definition of process is broad. Howes' process falls well within its language since it is "a new use of a known process, machine ... composition of matter, or material." 35 U.S.C. §100(b) (1976).*

Indeed the change in the statute, Section 100(b), of the Patent Act of 1952 overturned the former doctrine that new uses of old materials and processes were not patentable and in fact provided for the patentability of new uses of known processes, materials or compositions, most significantly in the area of biological inventions, i.e., in particular for new uses of chemicals and compositions thereof exhibiting new needed medicinal or therapeutic capability. As has been articulated, every biological activity is a natural and inherent result of the chemical structure from which it arises. The significant discovery in the area of biological inventions is in the identification of therapeutic activity of chemicals and compositions and consequently, their therapeutic value and utility. There is generally no reliable way of predicting utility for any medical indication based upon chemical formula

alone. Thus, only after extensive experimentation and testing can any therapeutic activity and thus, "use" be confirmed. The statute has thus provided for patentability of claims drawn to a method for using even an old or "obvious" drug composition, if the method has new and unobvious beneficial effects, even though the composition itself could not be patented since it has been prior disclosed for a different use. [See *In re Marshall* 578 F.2d 301, 198 USPQ 344 (CCPA 1978) and *In re Shetty*, 566 F.2d 81, 83, 195 USPQ 753, 754 (CCPA 1977)].

It is well established under US patent law that a second medicinal use of a substance already suggested or known to be useful in treating a human or animal disease is patentable as a method of use. As an example, Appellants cite the granting of US 6,100,270 (to Pfizer) with method claims for a second medicinal use, i.e., treating male erectile dysfunction, for sildenafil compositions, which have previously been patented for the treatment of other conditions including angina, hypertension and congestive heart failure (US 5,250,534). The method in the '270 patent involves the same method as the '534 patent, being oral administration of compositions containing the active sildenafil in overlapping dosages and frequency of administration. In '534, the method for the curative or prophylactic treatment of angina, hypertension or congestive heart failure involved administering oral dosages of the compounds generally in the range of from 4-800 mg daily for an average adult patient (70 kg) by using e.g., individual tablets or capsules containing from 2 to 400 mg of active compound, in a suitable pharmaceutically acceptable vehicle or carrier, for administration in single or multiple doses, once or several times per day. In '270 the claimed method for treating male erectile dysfunction involved administering oral dosages for a typical man of 15 to 225 mg daily such as using dosages of 5 to 75 mg of compound three times daily.

The second medicinal use is the basis for patentability of the same method previously used to treat a different medical condition, given that the method of the '270 patent is the same as the method of the '534 patent. Nothing in the statute requires that the method involve new or different steps, only that the method is for a new use, and such new use is not obvious.

The claim on such a new or second medicinal use can be properly claimed as a process or method. The present claims are directed to a new or second medicinal use (promoting whole body or systemic health in subjects at risk for the development of certain systemic conditions) of a known process (topical administration to the oral cavity to treat local conditions such as gingivitis and periodontal disease) and properly claimed as a method.

Appellants respectfully submit that the present claimed methods involving topically administering a composition comprising a H2 antagonist have new and unobvious beneficial effects, and are therefore patentable as **a new use of a process** even if such process were known. There is nothing in the teaching of the referenced art of the presently claimed second medicinal use of promoting systemic or whole body health by topical administration of H2-antagonist containing compositions.

Appellants further submit there is no evidence in the record to support the Examiner's finding that the referenced methods inherently anticipate the claimed invention of Claims 2 to 4 and 7. A finding of inherency requires that practicing the prior art method would necessarily and inevitably result in the claimed invention, i.e., promoting systemic or whole body health. Inherent anticipation must be established by more than mere probabilities or possibilities. An accidental or unwitting duplication of an invention may not constitute an anticipation. *In re Marshall* 578 F.2d 301, 198 USPQ 344 (CCPA 1978).

In *Marshall* (Id.), the US Court of Customs and Patent Appeals reversed the rejection of Marshall's claims on the grounds of anticipation because no single piece of prior art contained all the material elements of the claims and because the claims described a new and unanticipated use for an existing drug. Marshall's claims were directed to a process for controlling weight using an anesthetic drug, oxethazaine, to inhibit release of the pancreatic secretory hormones, secretin and pancreozymin, in order to control weight. The applied art was the *Physician's Desk Reference* (PDR), which taught using drugs containing the anesthetic oxethazaine to inhibit release of the acid-stimulating hormone, gastrin, in order to treat esophagitis, gastritis, peptic ulcer and irritable colon syndrome. There was no disclosure in the PDR of the activity of oxethazaine to inhibit release of the secretory

hormones, which activity makes it useful for losing weight. Therefore if a subject ever lost weight by following the PDR teachings it was an unrecognized accident. The CCPA stated:

> *An accidental or unwitting duplication of an invention cannot constitute an anticipation. In re Felton, 484 F.2d 495, 500, 179 USPQ 295, 298 (CCPA 1973).*

As in *Marshall*, the applied citations do not disclose the newly discovered activity of H2-antagonists when topically administered to the oral cavity, including increasing the barrier function of the gingival tissues and decreasing the blood levels of C-reactive protein and apolipoprotein B, such activity resulting in being useful to promote systemic or whole body health. If practicing the referenced methods promoted systemic health, it would be an accidental duplication of the present invention. Appellants respectfully submit that the applied citations do not constitute an anticipation of the present invention.

The Examiner correctly notes that the *Shetty* case cited by Appellants was concerned with a 103 rejection. *Shetty* is cited because of its relevance to the issue of inherency as it relates to biological or medicinal activity of chemicals and compositions and methods of use thereof. Case law supports the proposition that in the field of biological or medicinal inventions, inherency of the medicinal activity is not the material issue. Rather, it is whether or not such medicinal activity would have been recognized by those skilled in the art and applied to a new or second medicinal "use". There is lack of predictability of useful new results from simply the chemical structure of drug substances and their known activity.

Appellants further submit that the Examiner has not established a *prima facie* case of inherency as required under MPEP 2112 and 2131.02 Section III. As stated therein:

> *"In relying upon the theory of inherency, the examiner must provide a basis in fact and or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art."*

"The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish that result or characteristic."

To support the finding of inherency, the Examiner reasons that the presently claimed new use of promoting systemic health is a direct result of the antimicrobial mechanism of action of the referenced methods and that one of ordinary skill in the art would recognize that the referenced methods would reduce the quantity of oral pathogens in the oral cavity and that this in turn would reduce the quantity of pathogens entering the bloodstream from the gums and that reduction of said pathogens in the blood would promote systemic or whole body health.

Appellants respectfully submit that such conclusion of inherency is based upon improper hindsight reasoning. There is absolutely no teaching in the referenced art relating to the possibility that pathogens in the mouth and bacterial toxins could enter the systemic circulation via the gums, that such entry would be a risk factor for development of systemic diseases by prompting contributory systemic inflammatory mechanisms and complications and that such risk factor would be decreased by topically administering a H2-antagonist. As established in the record from the declaration by present inventor Robert E. Singer, Jr. (submitted in the response dated June 24, 2002 to the Office Action dated December 27, 2001), topical treatment of oral tissues with H2 antagonists serves to increase the barrier function of gingival tissues. The series of studies conducted under Mr. Singer's direction demonstrated that topical H2 antagonists enhance the barrier or protective function of gingival tissues thereby preventing oral pathogens and their products from entering into the systemic circulation. Topical administration of H2 antagonist compositions to the oral cavity further serves to decrease the blood levels of C-reactive protein and apolipoprotein B, such activity resulting in being useful to promote systemic or whole body health.

The referenced art teach nothing more than that H2 antagonists are useful in treating and preventing inflammations in the oral cavity such as gingivitis and periodontitis. Nothing is said in the references about reducing the quantity of oral pathogens or bacterial toxins in the mouth, much less that these oral pathogens and toxins could pose a risk to

systemic health if entry into the systemic circulation occurred and even less that H2-antagonists would enhance the barrier or protective function of gingival tissues and prevent such entry and would decrease the blood levels of C-reactive protein and apolipoprotein B. Without the benefit of the present disclosure, it would not be recognized that topical administration of selected H2-antagonists would have such biological capability and be effective to promote systemic or whole body health by reducing risk factors subjects for the development of particular systemic diseases.

CONCLUSION

Appellants respectfully request that the amendment to the claims and the remarks be made of record in the instant application. Appellants submit that the method of promoting whole body health defined by Claims 2-4 and 7 as amended is patentably distinct from Pan et al., Singer et al. and Tsujita, et al. Accordingly, the rejection of Claims 2-4 and 7 under 35 USC §102(b) should be reversed. Favorable action by the Board is respectfully requested.

Respectfully submitted,
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